REMARKS

The Office Action of September 24, 2009, has been received and reviewed.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 were previously pending and under consideration in the above-referenced application. Each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 has been rejected.

New claims 81-88 have been added.

Reconsideration of the above-referenced application is respectfully requested.

Claim Objections

The Office has objected to claim 62 because of typographical errors in that claim. The typographical errors in claim 62 have been corrected. Accordingly, the objection to claim 62 should be withdrawn.

Rejections under 35 U.S.C. § 112, First Paragraph

Written Description/New Matter Rejections

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, 59-71, 79, and 80 stand rejected for allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Specifically, the Office has objected to use of the terms "vitamin-like substance" and "herb or plant extract" in the claims.

"[T]here is no *in haec verba* requirement..." M.P.E.P. § 2163. In addition to providing an express basis for newly added claim limitations, the specification may also provide an implicit or inherent basis for such limitations. *Id.*

"The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A 'representative number of species' means that the species which are adequately described are representative of the entire genus." M.P.E.P. §2163.05(I).

"Consisting Of"

It has been asserted that the as-filed specification of the above-referenced application does not "disclose any embodiment supporting the transitional phrase of 'consisting of,'" which affects claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, 59-71, 79, and 80. Office Action of September 24, 2009, page 8.

It is respectfully submitted that paragraph **[0031]**, which discloses an "EXEMPLARY COMPOSITION," provides support for the subject matter recited by each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, 59-71, 79, and 80.

With respect to independent claim 1, as well as its dependent claims 4-8, 11, 12, 14-16, and 18, paragraph **[0031]** of the as-filed specification discloses a nutritional supplement that consists of "at least one vitamin" (vitamin A, vitamin C, vitamin E, niacin, vitamin B_6, folate, vitamin B_{12}), "at least one mineral" (magnesium, zinc, selenium, copper, potassium), at least one herb or plant extract" (butcher's broom, ginkgo biloba, hawthorn, garlic, red yeast rice extract, reservatrol, ginger oil), and "a cardiovascular support component" that consists of "an inflammation-reducing component" (transfer factor), "at least one low density lipoprotein (LDL) receptor-binding component" (magnesium lysinate), "at lesat one blood cholesterol reduction component" (niacin/niacinamide), "at least one blood flow-enhancing component" (magnesium arginate, niacin), and "at lesat one antioxidant" (coenzyme Q_{10}, vitamin A, vitamin C, vitamin E).

Paragraph **[0031]** of the as-filed specification also discloses an embodiment of a nutritional supplement meeting the limitations of independent claim 50 and its dependent claims 53-57, and 59-67; *i.e.,* a nutritional supplement which consists of "at least one vitamin" (vitamin A, vitamin C, vitamin E, niacin, vitamin B_6, folate, vitamin B_{12}), "at least one antioxidant" (coenzyme Q_{10}, vitamin A, vitamin C, vitamin E), "at least one mineral" (magnesium, zinc, selenium, copper, potassium), "at least one herb or plant extract" (butcher's broom, ginkgo biloba, hawthorn, garlic, red yeast rice extract, reservatrol, ginger oil), and "a cardiovascular support component" that consists of "a pathogen-reducing component" (transfer factor) and "at least one blood flow-enhancing component" (magnesium arginate, niacin).

As for independent claim 68 and its dependent claims 69-71, paragraph **[0031]** of the as-filed specification discloses an embodiment of a nutritional supplement that consists of "at least one vitamin" (vitamin A, vitamin C, vitamin E, niacin, vitamin B_6, folate, vitamin B_{12}), "at least one antioxidant" (coenzyme Q_{10}, vitamin A, vitamin C, vitamin E), "at least one mineral" (magnesium, zinc, selenium, copper, potassium), "at least one herb or plant extract" (butcher's broom, ginkgo biloba, hawthorn, garlic, red yeast rice extract, reservatrol, ginger oil), and "a cardiovascular support component" that consists of " a preparation including avian transfer factor…" (transfer factor), "Vitamin C," "niacinamide," an arginine-containing compound" (magnesium arginate), and "a lysine-containing compound" (magnesium lysinate).

All of the ingredients listed in independent claims 79 and 80 are present in the EXEMPLARY COMPOUND disclosed by paragraph **[0031]** of the as-filed specification.

In view of the foregoing, it is respectfully submitted that a careful comparison of the EXEMPLARY COMPOSITION disclosed by paragraph **[0031]** of the as-filed specification "consists of" all of the ingredients required by each of independent claims 1, 50, 68, 79, and 80. It is, therefore, respectfully submitted that the as-filed specification provides an adequate written description of the subject matter recited by (including the inclusion of "consisting of" in) each of these claims, and that each of these claims and their respective dependent claims therefore complies with the written description requirement of the first paragraph of 35 U.S.C. § 112.

"Vitamin-Like Substance"

In an effort to advance prosecution of the above-referenced application, "vitamin-like substance" has been removed from each of claims 1, 50, 62, 66, and 68, rendering the rejections of these claims and their dependent claims (if any) moot.

"At Least One Herb or Plant Extract"

As for the recitation of "at least one herb or plant extract," it is respectfully submitted that one of ordinary skill in the art would readily understand when a substance is an herb or a plant extract. More specifically, from the written description provided by the as-filed specification of the above-referenced application, it is apparent that the inventors were, at the earliest date to

which a claim for priority has been made in the above-referenced application, in possession of compositions that broadly include herbs or plant extracts, particularly when the herbs or plant extracts support cardiovascular health, as recited by each of amended independent claims 1, 50, and 68.

In this regard, the as-filed specification provides a representative number of examples of herb and plant extracts that support cardiovascular health, including butcher's broom (identified as a "root" by the as-filed specification); Ginkgo biloba (identified as a "leaf" by the as-filed specification); hawthorne (identified as including portions of a "flower" and a "leaf" by the as-filed specification); garlic (identified as including a "deodorized clove" by the as-filed specification); reservatrol (identified by the as-filed specification as coming from *Polygonum cuspidatum*, a well known herb); and ginger oil (ginger is a well known root).

In view of representative examples provided by the disclosure of the above-referenced application, it is respectfully submitted that the as-filed specification provides an adequate written description of "at least one herb or plant extract that supports cardiovascular health." Thus, it is respectfully submitted that, with respect to the subject matter recited by each of amended independent claims 1, 50, and 68, the as-filed specification complies with the written description requirement of the first paragraph of 35 U.S.C. § 112.

As neither "vitamin-like substance" nor "at least one herb or plant extract" appears in either independent claim 79 or independent claim 80, it is respectfully submitted that application of the 35 U.S.C. § 112, first paragraph, written description rejections to these claims is improper. Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, written description rejections of independent claims 79 and 80 is respectfully solicited.

Claim 59 has been rejected under the written description requirement of the first paragraph of 35 U.S.C. § 112 for reciting that at least one mineral comprises an LDL receptor-binding component. It is respectfully submitted that by describing "magnesium lysinate," a known mineral, as an LDL receptor-binding element, paragraph **[0023]** of the as-filed specification provides support for the subject matter recited by claim 59. Therefore, it is

respectfully submitted that claim 59 is drawn to subject matter supported by an adequate written description in the as-filed specification, as required by the first paragraph of 35 U.S.C. § 112.

In rejecting claim 62 under 35 U.S.C. § 112, first paragraph, the Office alleged that the as-filed specification does not provide an adequate written description of at least one mineral that comprises an antioxidant. It is respectfully submitted that by describing "magnesium dehydroascorbic acid," a known mineral, as an antioxidant, paragraph **[0037]** of the as-filed specification provides support for the subject matter to which claim 62 is directed. Accordingly, it is respectfully submitted that claim 62 is directed to subject matter supported by an adequate written description in the as-filed specification, per the requirements of the 35 U.S.C. § 112, first paragraph.

Enablement Rejections

Claims 59, 60, and 62-65 stand rejected for allegedly failing to comply with the enablement requirement of the first paragraph of 35 U.S.C. § 112.

In rejecting claims 59 and 60, the Office asserted that "lysine is not a mineral." Office Action of September 24, 2009, page 10. Notably, prior to the amendment presented above, claim 60 recited that the LDL receptor-binding component of claim 59 "comprises lysine." As "comprising" is an open-ended term, an LDL receptor-binding component that comprises a lysine may also comprise a mineral. In fact, the as-filed specification of the above-referenced application enables such LDL receptor-binding components. *See, e.g.,* paragraphs **[0023]**, **[0031]**, and **[0035]**. In any event, "lysine" has been removed from dependent claim 60, rendering moot the rejections of claims 59 and 60. Therefore, claims 59 and 60 are drawn to subject matter that is enabled by the as-filed specification, as required by the first paragraph of 35 U.S.C. § 112.

As for its rejections of claims 62-65, the Office has asserted that the "specification fail[s] to disclose that the mineral [of claim 62] comprises an antioxidant such as beta-carotene, vitamin A, vitamin E, or Co Q10." Office Action of September 24, 2009, page 11. Claim 62 recites that *at least one of* at least one vitamin, at least one mineral, or at least one herb or plant extract comprises at least a portion of at least one antioxidant. Thus, the at least one mineral

need not comprise beta-carotene, vitamin A, vitamin E, or Coenzyme Q_{10}. Instead, the at least vitamin or the at least one herb or plant extract could comprise one of these elements. In fact, beta-carotene, vitamin A, and vitamin E are known vitamins. Moreover, since claim 65 recites that the at least one antioxidant "comprises" Coenzyme Q_{10}, it is apparent that the at least one antioxidant is not limited to a certain component or a closed list of components, it may also include something other than a vitamin, a mineral, or an herb or plant extract—for example, Coenzyme Q_{10}. This notion is enabled by paragraphs **[0028]** and **[0037]** of the as-filed specification. For these reasons, it is respectfully submitted that the as-filed specification enables the subject matter recited by claims 62-65, as required by the first paragraph of 35 U.S.C. § 112.

In view of the foregoing, withdrawal of the 35 U.S.C. § 112, first paragraph, rejections of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, 59-71, 79, and 80 is respectfully requested, as is the allowance of each of these claims.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78 stand rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is purportedly not patentable over teachings from U.S. Patent 6,203,818 to Vester (hereinafter "Vester"), in view of teachings from Kirkpatrick, *"Properties and Activities of Transfer Factor,"* J. Allergy & Clin. Immunol., 55(6):411-421 (1975) (Abstract) (hereinafter "Kirkpatrick"), Campbell et al., *"Chlamydia pneumonia and Cardiovascular Disease"*, Emerging Infectious Diseases, 4(4):571-579 (1998) (hereinafter "Campbell"); U.S. Patent 6,506,413 to Rath et al. (hereinafter "Rath"), Tentolouris et al., *"L-Arginine in coronary atherosclerosis,"* Int'l J. Cardiol., 75:123-128 (2000) (hereinafter "Tentolouris"); Kemper, Ginger (Zingiber officinale), Longwood Herbal Task Force: http://www.mcp.edu/herbal/default.html 1999, pp. 1-18 (hereinafter "Kemper"); and U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also "be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

It is respectfully submitted that the Office has not articulated any specific reason for one of ordinary skill in the art to have combined teachings from Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, and Tokoro to develop a nutritional supplement that consists of all of the elements recited by any of independent claims 1, 50, or 68.

The teachings of Vester relate to nutritional supplements that include flavonoids (specifically quercetin) and folic acid for promoting cardiovascular health.

The teachings of Kirkpatrick relate to substantially pure transfer factor. Kirkpatrick teaches against transfer factor mixed with other substances. *See* col. 3, line 28, to col. 4, line 12.

Campbell discusses the role of *Chlamydia pneumonia* in cardiovascular disease.

Rath teaches the use of lysine-based substances conjunction with antioxidants, such as ascorbic acid and tocopherols, to prevent and/or treat cardiovascular disease.

Tentolouris suggests that L-arginine may be used to treat subjects at risk for atherosclerosis.

The teachings of Kemper relate to the use of ginger in treating a variety of conditions, including high cholesterol.

The teachings of Tokoro are limited to a transfer factor-like substance that those of ordinary skill in the art recognize as something other than transfer factor.

It is respectfully submitted that there are a number of reasons that the teachings of these references do not support a *prima facie* case of obviousness against any of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, or 59-78.

With respect to claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78, it is respectfully submitted that Kirkpatrick teaches away from combining its teachings with those of Vester, Campbell, Rath, Tentolouris, Kemper, and Tokoro in the manner that has been asserted. Specifically, Kirkpatrick teaches away from compositions that include transfer factor in addition to other ingredients, as such ingredients would apparently interfere with the characterization and stability of transfer factor. Col. 4, lines 49-64.

In addition, with respect to the subject matter recited by independent claims 1, 50, and 68 and, thus, by their dependent claims 4-8, 11, 12, 14-16, 18, 53-57, 59-67, and 69-71, it is respectfully submitted that none of Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, or Tokoro appears to teach or suggest a composition that includes at least one mineral.

Moreover, while Campbell teaches that *Chlamydia pneumonia* causes acute respiratory disease, none of the references that have been relied upon in rejecting claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78 teaches or suggests a composition that includes transfer factor that is specific for *Chlamydia pneumoniae,* cytomegalovirus, or *Heliobacter pylori,* as is required of the compositions recited by amended independent claim 1, amended independent claim 50, and amended independent claim 68.

As for the subject matter to which independent claim 72 and its dependent claims 73-78 are drawn, none of Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, or Tokoro, taken alone or in any combination, teaches or suggests a composition that includes a preparation including transfer factor and vitamin C ***in the same amounts***.

The Office has asserted that it would have been *obvious* for one of ordinary skill in the art *to optimize* the amounts of the ingredients recited by independent claim 72. Office Action of September 24, 2009, page 14. Thus, the Office has relied upon the "obvious to try" rational set forth by M.P.E.P. § 2143(E). Further, since no single reference cited by the Office combines

transfer factor with vitamin C, the Office has relied upon the "Combining Prior Art Elements" rationale of M.P.E.P. § 2143(A).

The Combining Prior Art Elements rationale requires that the Office articulate some reasoning as to why one of ordinary skill in the art would have recognized that the results of combining transfer factor and vitamin C would have been predictable. M.P.E.P. § 2143(A). Unfortunately, the Office has not articulated any such reasoning.

The Obvious to Try rationale requires the Office to articulate: (1) a finding that there was a recognized problem or need in the art; (2) a finding that there were a finite number of identified, predictable solutions; and (3) a finding that one of ordinary skill in the art could have pursued the predicted potential solutions with a reasonable expectation of success. M.P.E.P. § 2143(E). Again, the Office has not established that one of ordinary skill in the art would have believed that there would be any benefit in combining transfer factor with vitamin C and, out of all of the many potential combinations, predict the utility of combining the same amounts of transfer factor and vitamin C with one another.

Further, none of the cited references teaches or suggests a composition that includes transfer factor and vitamin C in the same amounts.

Therefore, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness against independent claim 72 or any of its dependent claims 73-78.

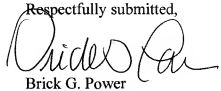
In view of the foregoing, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness against any of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, or 59-78, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

CONCLUSION

It is respectfully submitted that each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be

resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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